510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
K060783

B. Purpose for Submission:
To remove a limitation for the detection of vancomycin resistant *Staphylococci aureus* (VRSA) on Sensititre® 18-24urs MIC susceptibility plates.

C. Measurand:
Vancomycin at 1-128 µg/mL

D. Type of Test:
Antimicrobial Susceptibility Test (Quantitative and Qualitative) growth-based fluorescence

E. Applicant:
TREK Diagnostic Systems INC.

F. Proprietary and Established Names:
Sensititre 18-24 hours MIC susceptibility plates

G. Regulatory Information:

1. Regulation section:
   21 CFR 866.1640 Antimicrobial Susceptibility Test Powder
2. Classification:
   Class II
3. Product Code:
   JWY-manual readings of AST testing of >16 hour incubation
   LRG Automated readings of AST of >16 hour incubation
4. Panel:
   83 Microbiology

H. Intended Use:

1. Intended use(s):
   Vancomycin at 1-128 µg/mL for use with gram positive organisms including VRSA with the Sensititre® MIC Susceptibility system is an *in vitro* diagnostic product for clinical susceptibility testing of gram negative and gram positive organisms.

2. Indication(s) for use:

This submission is for the removal of the limitation for the detection of VRSA with the antibiotic Vancomycin at 1-128 µg/mL on the Sensititre® 18-24 hour MIC susceptibility plates for testing staphylococcus.

3. Special condition for use statement(s):

   The Sensititre® Gram Positive AST panel detected vancomycin resistance in the VRSA *S. aureus* strains available at the time of comparative testing. The ability to detect resistance in other *S. aureus* strains is unknown due to the limited number of resistant strains available for comparative testing.

   Prescription Use Only

4. Special instrument Requirements:
   Not Applicable

I. Device Description:

Sensititre® MIC Susceptibility plate MIC panels are multi-well plastic microtitre plates, precision dosed with dried, stabilized antimicrobics. This is a modification of a microversion of the classic broth dilution methods and can provide both qualitative and quantitative susceptibility results.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Pasco MIC and MIC/ID Panels

2. Predicate K number(s):
   K033119

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended use	an *in vitro* diagnostic product for clinical susceptibility testing of gram negative and gram positive organisms.	same
Inoculum	Prepared from colonies using the direct inoculation method	Prepared from colonies using the direct inoculation method
Inoculation method	Direct equated to a 0.5 McFarland	Direct equated to a 0.5 McFarland
Item	**Device**	**Predicate**

Type panel	Dried antibiotics	100 µl/well frozen
Incubation	18-24 hours	16-24 hours
Technology	Fluorescence detection of growth	Turbidity detection of growth
Reading method	Visual growth and Auto read by instrumentation	Visual growth

K. Standard/Guidance Document Referenced (if applicable):

"Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA"; CLSI M7 (M100-S16) "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard."

L. Test Principle:

The Sensititre® Autoread System utilizes fluorescence technology to read 18-24 hour plates. The technology involves the detection of bacterial growth which is determined by generating a fluorescent product form a non-fluorescent substrate. The non-fluorescent substrate is prepared by conjugating a fluorescent compound to the specific enzyme substrates with a bond which prevents fluorescence. The substrate is added to the inoculum broth and dispensed into the test plates at the same time as the test organism. The amount of fluorescence detected is directly related to the activity of bacterial growth. The MIC is determined by observing the lowest dilution of antimicrobial agent that inhibits growth of the organism. Final results may also be read manually after 18-24 hour incubation by visual observation of turbidity without the use of the fluorescence.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. ***Precision/Reproducibility***

Intersite and Intrasite testing demonstrated >95% reproducibility using 29 strains. The 25 isolate study described in the guidance document was used. These were tested 1 time at each of three sites on each reading method.

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or method):

Ability to provide acceptable Quality Control with the recommended strains was established previously with additional testing during the study. Comparison was made to expected values as established for the well characterized strains.

Nephelometer was used at each site to standardize the inoculum and it was calibrated each time it was switched on. Colony counts were performed on the quality control isolate with acceptable results for all.

d. Detection limit:
Not applicable

e. Analytical specificity:
Not applicable

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A well characterized challenge set of 35 staphylococci with all but 6 having MICs in the range of testing of vancomycin was used for the evaluation. The testing was performed on the Sensititre® panel and compared to results using the broth reference method. Additionally 6 known VRSA clinical isolates were also tested on the Sensititre® Gram Positive AST Panel with results that were >32 for all isolates. The combined Essential Agreement (EA) for all 41 isolates tested was 100% and the Category Agreement (CA) was 95% with no major or very major errors. Performance was similar when readings were performed manually or on an automatic reader. There was no apparent trending of results for either read method as compared to the reference result.

b. Matrix comparison:
Not applicable

3. Clinical studies:

a. Clinical sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data (when a and b are not applicable):
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:

Interpretative criteria – $\leq$ 4 μg/ml (S) 8-16 μg/ml (I) and $\geq$ 32 μg/ml (R)

N. Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

Vancomycin MIC of $\geq$ 4 µg/mL are recommended for follow up because this is considered an unusual result for staphylococcus.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.